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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/972,035 | 10/04/2001 | Daniel Albert Wettstein | 1907.03 | 2866 |

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MYRIAD GENETICS INC.
LEGAL DEPARTMENT
320 WAKARA WAY
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EXAMINER

HILL, MYRON G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,035

Applicant(s)

WETTSTEIN ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 64 is/are pending in the application.
- 4a) Of the above claim(s) 24- 43 and 51- 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 23, 44- 50, and 61- 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 14, 15.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Amendment C, filed 9/29/03.

Claims 1- 23 and 44- 50 are under consideration in this action.

Election/Restrictions

Applicant requests that claim 26 be included in the elected invention because it has been amended to be "substantially identical" to the protein complex of claim 1. The amended form of the claim was not presented in the amended claim set and cannot be considered by the examiner. The examiner will consider including the claim if presented in the next response with the claim set.

Information Disclosure Statement

Signed and initialed copies of IDS papers #14 and 15 (filed June 26, 2003 and September 19, 2003, respectively) are enclosed.

Objection/Rejections Withdrawn

Specification

The specification has been amended to remove the hyperlinks and the objection is withdrawn.

The rejection of claims 44- 50 under 35 U.S.C. 103(a) as being unpatentable over Ott as applied to claims 1- 8, 12- 15, 17- 20, and 22 above, and further in view of Heinrichs is withdrawn.

The cited art does not meet the limitations of the claims after consideration of applicant's arguments.

Rejections Maintained

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 23 and 44- 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the terms "homologue", "derivative", and "fragment" are not clear.

Applicant argues that the definition of homology is clear as to what is required, that the structure is similar and interact through the same domain as the interactor, and amended the claim so that it is required to be 50% identical.

Applicant's arguments have been fully considered and not found persuasive.

Applicant deleted the term derivative from the claims.

It is not clear what structure is required to be 50% and there is no domain recited in the claims. Without a reference to a SEQ ID# it is not clear what is meant by the function recited. See new rejections below.

The term fragment was not addressed in the response. Without knowing what structure is required, the metes and bounds of fragment are not clear.

"Homologue" and fragment are still not clear.

Claim Rejections - 35 USC § 102

Claims 1- 8, 12- 15, 17- 20, and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ott.

Applicant argues that ubiquitin does not have an EUV domain, that ubiquitin does not bind gag in the same way as TSG101, and that ubiquitin only shares 7.4% sequence homology and is not a homologue.

Applicant's arguments have been fully considered and not found persuasive.

The claims do not recite a domain or specific binding site. The protein of Ott contains several short fragments that are over 4 residues long that are 100% identical to TSG101 and binding can be based on those fragments. The claims only require fragments. Because the metes and bounds of the term fragment are not clear, the rejection is maintained.

Thus, Ott anticipates the invention.

Claim Rejections - 35 USC § 103

Claims 9- 11, 16, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ott as applied to claims 1- 8, 12- 15, 17- 20, and 22 above, and further in view of Desai.

Applicant argues that ubiquitin does not bind gag in the same way as TSG101.

Applicant's arguments have been fully considered and not found persuasive.

The claims do not recite a domain or specific binding site. The protein of Ott contains several fragments that are over 4 residues long that are 100% identical to TSG101 and binding can be based on those fragments. Because the metes and bounds of the term fragment are not clear, the rejection is maintained.

Thus, Ott and Desai anticipate the invention.

Rejections Based On Amendments or Newly Added Claims

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 4, and 61- 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1- 4 it is not clear what defines 50% because there is no definite structure to base the 50% on.

In claims 61- 64, it is not clear what the metes and bounds of UEV domain are. It is not clear what the term fragment means, see at least claim 61 (b)(2) and rejection above. Also, in at least claim 61 (a)(iv), it is not clear what "said TSG101" refers to in the list of TSG101s. The term in at least claim 61 (b)(1) "HIV GAG polypeptide" does not define what comprises the polypeptide.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
March 20, 2004


JAMES HOUSEL 3/22/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600